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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/940,925   | 08/28/2001  | James E. Dahlberg    | FORS-06612          | 6817             |
| 23535  | 7590        | 10/28/2004           | EXAMINER            |                  |
| MEDLEN & CARROLL, LLP<br>101 HOWARD STREET<br>SUITE 350<br>SAN FRANCISCO, CA 94105 |             |                      | SULLIVAN, DANIEL M  |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1636                |                  |

DATE MAILED: 10/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/940,925

Applicant(s)

DAHLBERG ET AL.

Examiner

Daniel M Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 71-80,82-84 and 86-94 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 71,72,80,82,83,86,89,90 and 93 is/are rejected.
- 7) ☒ Claim(s) 73-79,84,87,88,91,92 and 94 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 March 2004 and 21 May 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 17 September 2004 has been entered.

Claims 71-94 were pending and under consideration in the Final Office Action mailed 16 January 2004. Claims 81 and 85 were canceled and claim 71 was amended in the 17 September Paper. Claims 71-80, 82-84 and 86-94 are presently pending and under consideration.

### ***Response to Amendment***

Rejection of claims 81 and 85 is rendered moot by the cancellation thereof.

### **Drawings**

Objection to the drawings is withdrawn.

### **Claim Rejections - 35 USC § 102**

Rejection of claims 71-75, 77-80, 87, 88 and 92-94 under 35 U.S.C. 102(b) as being anticipated by US 4,994,368 (Goodman et al.) is withdrawn.

### **Claim Rejections - 35 USC § 103**

Rejection of claims 71-80, 87, 88 and 92-94 under 35 U.S.C. §103(a) as being unpatentable over US 4,994,368 (Goodman et al.) is withdrawn.

Rejection of claims 71-80, 82-84, 86-88 and 92-94 under 35 U.S.C. §103(a) as being unpatentable over US 4,994,368 (Goodman et al.) in view of US 5,994,056 (Higuchi et al.) and further in view of US 5,210,015 (Gelfand et al.) is withdrawn.

Rejection of claims 71-80, 82-84 and 86-94 under 35 U.S.C. 103(a) as being unpatentable over Goodman et al.) in view of US 5,994,056 (Higuchi et al.) and further in view of US 5,210,015 (Gelfand et al.) as applied to claims 71-88 and 92-94, and further in view of US 4,935,357 (Szybalski) is withdrawn.

### ***New Grounds***

#### **Claim Objections**

Claim 90 is objected to because of the following informalities: The phrase "said portion said third oligonucleotide hybridized" is grammatically incorrect. It is recommended that the phrase be amended to read, "said portion of said third oligonucleotide hybridized". Appropriate correction is required.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 71, 72, 80, 82, 83, 86, 89, 90 and 93 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3 and 7 of U.S. Patent No. 5,691,142. Although the conflicting claims are not identical, they are not patentably distinct from each other because the limitations of the '142 patent fall entirely within the scope of the instant claims except for the limitation of the cleavage means to comprising a 5' nuclease, which would be obvious to one of ordinary skill in the art based on the definition of cleavage means in the '142 patent disclosure.

The instant claims are directed to a method comprising mixing a cleavage means comprising a 5' nuclease with a target nucleic acid and a first and second nucleic acid under conditions such that a 3' portion of the first oligonucleotide is hybridized to a first region of the target nucleic acid and at least a portion of the second oligonucleotide is hybridized to a second region of the target nucleic acid to form a complex which is cleaved to liberate the 5' portion of the first oligonucleotide as a cleavage product. These limitations are anticipated by parts (b) and (c) of claim 1 of the '142 patent except for the limitation of the cleavage means to comprising a 5' nuclease. However, column 13 of the '142 patent teaches, "[t]he modified thermostable DNAPs of the invention form the basis of a novel detection assay for the identification of specific nucleic acid sequences" and column 9 teaches, "[i]n particular, the present invention relates to a cleaving enzyme having 5' nuclease activity without interfering nucleic acid

synthetic ability.” As the cleavage means having 5’ nuclease activity is explicitly identified as “the basis” of the detection assay, the cleavage means cannot be considered a patentable distinction. One of ordinary skill in the art would be motivated to use a 5’ nuclease as the cleavage means in the method claimed in the ‘142 application because the 5’ nuclease is clearly the preferred embodiment of the cleavage means.

The method of the instant claims is further limited to reacting the first cleavage product with a third oligonucleotide and the cleavage means such that a portion of the first cleavage product is hybridized to the third oligonucleotide to form a second complex, wherein cleavage of the second complex generates a second cleavage product, which second cleavage product is detected. These steps are anticipated by parts (d)-(h) of the ‘142 patent claim 1. Thus, the limitations of the instant claim 71, as a whole, would be obvious to one of ordinary skill in the art at the time of filing.

Furthermore, the limitations of claims 72, 89, 90 and 93 are also anticipated by, and therefore obvious over, the limitations of claim 1 of the ‘142 patent. In the ‘142 patent: the second cleavage product is detected, albeit indirectly, thorough additional hybridization and cleavage steps (parts (c)-(h)) according to the instant claim 72; the third oligonucleotide comprises a hairpin structure that comprises a duplex region adjacent to a single stranded 3’ arm (part (d)) according to the instant claim 89; the portion of the third oligonucleotide hybridized to the portion of the first cleavage product comprises a region of the single stranded 3’ arm of the hairpin structure (part (d)) according to claim 90; and the cleavage of the second complex cleaves the third oligonucleotide according to claim 93.

The limitation of the instant claim 80, which requires that the third oligonucleotide is attached to a solid support is anticipated and rendered obvious by claim 7 of the '142 patent. Likewise the limitations of claims 82, 83 and 86, which require that the enzyme comprising a 5' nuclease is a thermostable DNA polymerase and modified to have reduced synthetic activity, are rendered obvious by recitation of the same limitations in claim 3 of the '142 application.

For these reasons, the invention claimed in claims 71, 72, 80, 82, 83, 86, 89, 90 and 93 as a whole would have been obvious to one of ordinary skill in the art based on claims 1, 3 and 7 of the '142 patent. Therefore, the claims are rejected under the judicially created doctrine of obviousness double patenting.

#### ***Allowable Subject Matter***

Claims 73-79, 84, 87, 88, 91, 92 and 94 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'D. Sullivan', with a long horizontal flourish extending to the right.

Daniel M Sullivan, Ph.D.  
Examiner  
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